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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,970	06/30/2006	Leona Gabrizova	MHOL-P-004	3352
57380                      7590                      08/11/2008 Oppedahl Patent Law Firm LLC P.O. BOX 4850 FRISCO, CO 80443-4850				
EXAMINER				
MANOHEAR, MANU M				
ART UNIT		PAPER NUMBER		
4161				
NOTIFICATION DATE		DELIVERY MODE		
08/11/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-oppedahl@oppedahl.com

# Office Action Summary

**Application No.**

10/596,970

**Applicant(s)**

GABRIZOVA, LEONA

**Examiner**

MANU MANOHAR

**Art Unit**

4161

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date June 30, 2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **The status of the Claims**

Claims 6-17 in this application are pending.

### **Priority**

The priority date for this application is January 14, 2004.

### ***Claim Rejections - 35 USC § 101 and 112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-17 drawn to the use of composition, preparation of composition for cosmetic, pharmaceutical and foodstuff products however the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14- 17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 6 - 13 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 is drawn to a method of preparation of a fungal glucan hydrogel having antibacterial and immunostimulant activity by alkaline subsequent elimination of water-soluble components, characterized in that the obtained insoluble glucan is subsequently hydrated by wet grinding at a rotational speed of 3000 to 9000 rpm for 10 to 20 minutes to a swelling volume in water of 50 to 500 ml/g, and finally it is adjusted by heat sterilization at a temperature of 90 to 110 degrees C. for 20 to 30 minutes, resulting in a gel which is formed by fungal polysaccharide with the .beta.-(1,3)-D-bond in the principal chain, with a concentration of 0.5 to 3% by weight.

This preparation of the product does not recite any constituents or starting materials but state the steps involved in the preparation and provide description of the chemical nature of the end product. Further, line 2 recites "immunostimulant activity by alkaline subsequent elimination of water-soluble components". It is unclear if that recitation is referring to the activity, or a step involved in the preparation or the modification of the step and due to the ambiguity of this term the lines 3, 4 and 5 also

not clear. If it is referring to the product, then it is unclear what is comprised within the product for preparing the product.

Claim 7-13 are dependent claims of claim 6 drawn to the properties of the product. Since the claim 6 is being indefinite, fail to clearly claim the invention the claims 7-13 are also considered as indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheatcroft et al , US Patent 6,444,448, in view of Hunter et al , US Patent Application US 2002/0192280.

Claim 6 is not clear for reasons given above. However, the examiner considered the claims 6 -13 with the understanding that these claim state the method of preparation of glucan hydrogel from a fungi by manipulating the temperature and the water content.

Claim 6 is drawn to a method of preparation of a fungal glucan hydrogel having antibacterial and immunostimulant activity by alkaline (deproteination) and subsequent elimination of water-soluble components, characterized in that the obtained insoluble glucan is subsequently hydrated by wet grinding at a rotational speed of 3000 to 9000 rpm for 10 to 20 minutes to a swelling volume in water of 50 to 500 ml/g, and finally it is

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adjusted by heat sterilization at a temperature of 90 to 110 degrees C for 20 to 30 minutes, resulting in a gel which is formed by fungal polysaccharide with the beta-(1,3)-D-bond in the principal chain, with a concentration of 0.5 to 3% by weight.

Wheatcroft et al teaches the production of Beta-glucan with immunostimulatory activity (Abstract-line 1-3), anti-infective property (column 1-line 41-43, line 45-47). It also teaches that the preparation with water using homogenizer (wet grinding) which can result in the form viscous product (Column 10- line 65 to column 11- line 9). The glucan can also be prepared in the form of gel or cream (Column 12-line 66-67). The Beta glucan described by the Wheatcroft comprises a beta- 1, 3 bond (Column 1-line 32, column 17-claim 1, column 20-claims 24 and 25). Wheatcroft et al also teaches the use of water (10% and 20% of dry weight column 10-line 63-66) with varying temperature (column 11-line 46-49) for beta (1,3)-glucan preparation. It does not specifically teach the temperature range 90-110 degrees for 20 to 30 minutes. However it would be obvious to ordinary skill in the art to manipulate the temperature and time to develop the product of the interest.

Claim 7 is drawn to the method wherein the insoluble glucan is prepared from fruiting bodies of oyster mushroom (*Pleurotus ostreatus*).

Wheatcroft et al teaches that the beta glucan can be prepared from fungi *Pleurotus ostreatus* (column 5-line 21, column 18 claim 17).

Claims 8 and 9 are drawn to the method wherein the polysaccharides are with the beta-(1,3)-D-bond branched at every fourth anhydroglucose unit. Wheatcroft et al teaches that the beta glucans are formed from D-glucose with beta-1,3- and beta-1,6-

bonds and can vary in chain-length, molecular weight by its nature (Column 1-line 17-28). It does not specifically teach that the beta-(1,3)-D-bond branched at every fourth anhydroglucose unit, however it is obvious in the art to modify the branching structure to optimize biological activity.

Wheatcroft et al teaches that fungal glucan can have anti-infective property which can be prepared in the form of gel or cream. It also teaches the preparation from the oyster mushroom, *Pleurotus ostreatus*. It also teaches that the beta glucans are formed from D-glucose with beta-1,3- and beta-1,6- bonds and can vary in chain-length, molecular weight by its nature. It does not specifically teach that the beta-(1,3)-D-bond branched at every fourth anhydroglucose unit, Wheatcroft also does not specifically teach the use of benzoic acid in their preparation as a chemical sterilizer.

Claim 10 is drawn to the method of preparation of fungal glucan hydrogel which is chemically sterilized by addition of 0.02% of benzoic acid. Claim 11 is drawn to the method of preparation of glucan hydrogel from fruiting bodies of oyster mushroom and the resulting hydrogel is chemically sterilized by addition of 0.02% of benzoic acid. Claim 12 is drawn to the preparation of fungal polysaccharide with the beta (1,3)-D-bond branched at every fourth anhydroglucose unit and the resulting fungal glucan hydrogel is chemically sterilized by addition of 0.02% of benzoic acid. Claim 13 is drawn to the method preparation of the glucan from fruiting bodies of oyster mushroom which have beta -(1,3)-D-bond branched at every fourth anhydroglucose unit and this preparation is chemically sterilized by addition of 0.02% of benzoic acid.

Hunter et al teaches the use of benzoic acid and its derivatives to use as a preservative, chemical sterilizer, (page 10 paragraph [0072] in a composition including composition with beta glucan (Page 2 paragraph [0010] line 14). (Manu, what about

The combined teachings of Wheatcroft et al, in view of Hunter et al makes it prima facie obvious to one of ordinary skill in the art at the time of the invention to develop a glucan from a fungi for immunomodulatory and anti-infective purposes. Wheatcroft et al., teaches the preparation of fungal glucan hydrogel with antibacterial and immunostimulant activity and this hydrogel can be chemically sterilized using benzoic acid, as taught by Hunter et al. This would provide motivation to a person of ordinary skill in the art to develop the instant composition at the time of the invention. However the combined teachings do not specifically teach that the beta-(1,3)-D-bond branched at every fourth anhydroglucose unit, but it is obvious in the art for reasons given above. Furthermore, as evidenced by Hunter et al., benzoic acid is a well known preservative, the exact percentage of Benzoic acid added to composition for Benzoic acid to perform this function can be optimized by those of skill in the art and is therefore obvious absent any teaching to contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PATRICK Nolan can be reached on 571-272-0847. The fax phone number



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for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MANU MANOHAR  
Examiner  
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MM

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161